DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
FAX: 504-253-4566

December 18, 2000

WARNING LETTER NO. 2001-NOL-06

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Daniel Crowley, President and CEO
Coram Healthcare
1125 17th Street, Suite 2100
Denver, Colorado 80202

Dear Mr. Crowley:

During an inspection of your manufacturing facility, located at 115 James Drive West, Suite 100, St. Rose, Louisiana, conducted during August 23-September 20, 2000, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) requirement regulations. These deviations cause your drug product, liquid medical oxygen, to be adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The controls used for manufacture, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice requirement regulations [Title 21, *Code of Federal Regulations*, Parts 210 and 211 (21 CFR)].

Our inspection revealed the following CGMP deficiencies:

1. Failure to test incoming bulk Liquid Oxygen U.S.P., for identity and strength, or to assure the identity and strength of your incoming bulk Liquid Oxygen U.S.P., prior to filling liquid cryogenic home units [21 CFR 211.165(a)];

2. Failure to adequately test each batch of drug product prior to release for conformance to final specifications for the drug product [21 CFR 211.165(a)];

3. Failure to establish and maintain batch records documenting the manufacture, packaging, testing, and holding of each batch of drug product [21 CFR 211.188(b)];

4. Failure to establish written procedures that include the identification of drug product with a lot number that permits the determination of the history of the manufacture and control of the batch [21 CFR 211.130(c)];

5. Failure to establish quarantine areas for, or to segregate, the storage and holding of incoming Liquid Oxygen U.S.P., compressed Oxygen U.S.P. cylinders, finished Liquid Oxygen U.S.P. product cylinders, and rejected cylinders [21 CFR 211.42(b) & (c); 21 CFR 211.82(b); and, 21 CFR 211.142(a)];

6. Failure to provide training to employees who are involved in the manufacturing and/or supervision process [21 CFR 211.25(a) & (b)];

7. Failure to establish an adequate quality control unit having the responsibility and authority to approve or reject all components, drug product containers, closures, labeling, written procedures, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated [21 CFR 211.22(a)];

8. Failure to maintain records documenting pre-fill testing of cryogenic vessels, i.e. finished Oxygen U.S.P. containers [21 CFR 211.82(a) and 21 CFR 211.84(a)]; and,

9. Failure to have all drug product production and control records reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed [21 CFR 211.192].

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the CGMP requirement regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so they may take this information into account when considering the awarding of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection, on September 20, 2000, Ms. Teresa E. Kughn, Branch Manager, made a verbal commitment to correct the observed deficiencies. Our investigator documented Ms. Kughn's commitment by annotating the FDA 483 discussed with her on September 20, 2000. We are also in receipt of Ms. Kughn's letter, dated October 20, 2000, in which she made a written commitment to provide to us a written report documenting completion of your firm's corrective actions in response to the September 20, 2000, FDA 483. We have no record of any further correspondence from your firm.

It is necessary for you to notify this office in writing, within 30 days of receiving this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, please contact Ms. Asente.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosures: Form FDA 483
Ms. Kughn's October 20, 2000 Letter

cc: Ms. Teresa E. Kughn, Branch Manager
Coram Healthcare
115 James Drive West, Suite 100
St. Rose, Louisiana 70087